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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,387	02/13/2002	Harry Flewitt	C70376	1701

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EXAMINER

PICKETT, JOHN GREGORY

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,387

Applicant(s)

FLEWITT, HARRY

Examiner

Gregory Pickett

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☒ Claim(s) 26-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office action acknowledges Preliminary Amendment A, paper number 5, submitted 13 February, 2002.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the internal cavity directly enclosed by parts of the outer wall and in contact with the outer wall claimed in claim 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. The disclosure is objected to because of the following informalities: Page 1, line 6, "In particularly the invention..." is grammatically incorrect. Page 4, line 24, recites "such as mono-olein...", the "such as" appears to be a repetition of a previous "such as".

Page 4, line 27, "diglyceride" appears to be a typographical error. Page 8, line 3, a closing parenthesis is missing.

Appropriate correction is required.

Claim Objections

4. Claims 26-28 are objected to because of the following informalities: Claim 26, line 1, "diglyceride" appears to be a typographical error. Claim 27, Line 1 recites "claims 22", this appears to be a typographical error. Claim 28 is dependent on claim 27 and is objected to for the aforementioned reason. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The applicant does not describe the makings of a double walled container with a continuous base wall linking spaced apart inner and outer walls wherein the inner cavity is directly enclosed by parts of the outer wall and is in contact with the outer wall. Figure 2 of the present application does not disclose the outer wall enclosing the inner cavity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 16-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the body" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claims 17-21 and 29-30 are dependent on claim 16 and are rejected for the above reason.

Claim 22 is dependent on cancelled claim 1, cancelled by Preliminary Amendment A, paper number 5. To prosecute claim 22 on its merits, the examiner assumes the claim to depend on claim 16.

Claims 23-28 are dependent on claim 22 and are rejected for the above reason.

Further regarding claim 17, "the contents" in line 3 renders the claim indefinite since only one medicament content is claimed in claim 16.

Further regarding claim 19, it is indefinite as to whether the applicant is claiming the further limitation of substantially cylindrical inner and outer walls.

Further regarding claim 20, it is indefinite as to whether the applicant is claiming the further limitation of lower and upper container parts.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16, 20, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Meshberg (US 5,516,006).

Regarding claim 16, Meshberg discloses container 10 with base wall 34, side-walls 36 and 37 extending upwardly from the base wall (Figure 1, rotated 180°) toward upper mouth opening 15. Side-walls 36 and 37 are spaced apart inner wall 36 and outer wall 37, and are made of plastic material (Col. 4, ln 38-39). Meshberg anticipates a conventional decorative casing for the device (Col. 4, ln 32-34) which the examiner interprets as a label located on the outer surface of the outer wall, since labels located as such are conventional in the container art. Meshberg further anticipates an internal cavity containing a medicament content (Col 4, ln 19-22) and being bounded in part by inner wall 36. Base wall 34 is continuous and links inner wall 36 and outer wall 37, closing the space between them.

As to claim 20, Meshberg discloses lower part 32 and upper part 14 fitting together with a seal (Figure 1) with upper inner wall 16 and upper outer wall 31.

As to claim 30, Meshberg discloses a nasal dispenser with means 13 to deliver its medicament content to the nasal area of the user.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meshberg in view of Henkel et al. (WO 98/14189).

Meshberg discloses a container as applied to claim 16 above.

Meshberg does not disclose a medicament content that is a fluid incorporating a solvent vehicle. Nor does Meshberg disclose a medicament content incorporating a pharmaceutically acceptable oily vehicle of monoglyceride, phospholipid, or galactolipid. Meshberg also does not disclose an oily vehicle of glycerol mono-oleate, glycerol monopalmitate, or glycerol monostearate. Nor does Meshberg disclose a long chain diglyceride, or a fatty acid triglyceride of caprylic/capric triglyceride. And Meshberg does not disclose a medicament content of calcium mupirocin, fractionated coconut oil, and glycerol mono-oleate.

Henkel et al. discloses a nasal medicament incorporating a solvent vehicle (Page 6, In 20-21), said solvent vehicle comprising a pharmaceutically acceptable oily vehicle (Page 6, In 24) of the group comprising monoglyceride, phospholipid, or galactolipid (Page 5, In 27-30), or of the group comprising glycerol mono-oleate, glycerol monopalmitate, or glycerol monostearate (Page 5, In 35-37). Henkel et al. discloses a long chain diglyceride (Page 5, In 32-34), and a fatty acid triglyceride of caprylic/capric triglyceride (Page 6, In 34-38 and Page 7, In 1-4). Henkel et al. further discloses a medicament content comprising calcium mupirocin (Page 4, In 20-23), fractionated coconut oil (Page 9, In 15-17), and glycerol mono-oleate (Page 6, In 13-14).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the medicament of Henkel et al. in the container of Meshberg in order to apply the treatment of bacterial infection in the nasalpharynx directly to the nasal passages as suggested by Henkel et al. (Page 10, In 35-36).

9. Claims 16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still (US 2,494,456).

Regarding claim 16, Still discloses a double walled container (Figure 1) with base wall 17, side walls 10 and 11 extending upwardly from base wall 17 toward upper mouth opening 15, side walls 10 and 11 spaced apart with inner wall 10 and outer wall 11, internal cavity 21 containing a medicament content (Col. 1, In 1-4) and bounded in part by inner wall 10. Still discloses base 17 as continuous and linking inner wall 10 and outer wall 11 and closing the space between them.

Still does not disclose inner wall 10 and outer wall 11 made of plastics material, or a label located on the outer surface of the outer wall.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to fabricate the container of Still of plastic material in order to reduce the cost of fabrication. Plastic and glass are common and conventional in the container art. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a label on the outer surface of the outer wall for the obvious reason of identifying the contents of the container for the user.

As to claim 18, Still discloses side walls in the form of a continuous double wall extending the whole length of the internal cavity.

As to claim 19, the container of Still is cylindrical with concentric and coaxial inner and outer walls.

As to claim 20, Still anticipates upper and lower container parts in Figure 4. with upper inner wall 112 and upper outer wall 114 fitting together with lower inner wall 113 and lower outer wall 115 and forming a seal.

As to claim 21, Still discloses a container having an undisclosed wall thickness. Still does not disclose expressly an inner wall thickness ca. 1-2 mm and an outer wall thickness ca. 1-2.5 mm. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to fabricate the container of Still with an inner wall thickness ca. 1-2 mm and an outer wall thickness ca. 1-2.5 mm because applicant has not disclosed that the wall thickness claimed provides an advantage, is used for a particular purpose, or solves a stated problem. One of

ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a larger wall thickness because the walls of greater thickness would perform equally well the function of separating the inner and outer walls.

10. Claims 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Still in view of Henkel et al.

Still discloses a container as applied to claims 16, and 18-21 above.

Still does not disclose a medicament content as claimed by the applicant in claims 22-29.

Henkel et al. discloses a medicament content as disclosed above. Henkel et al. further teaches the storage of the medicament content as a kit in a single container with two parts separated by a barrier.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to store the medicament content of Henkel et al. in the container of Still as claimed by the applicant and suggested by Henkel et al. in order to provide separate compositions in a single container. The removal of inner lid 12 of Still would allow for mixing the components prior to use.

Conclusion

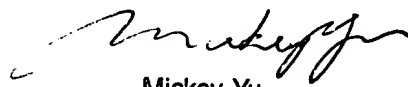
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 8:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-308-7769 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

GP
Gregory Pickett
Examiner
November 26, 2002


Mickey Yu
Supervisory Patent Examiner
Group 3700